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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/762,867 | 09/10/2001 | Hideaki Takahashi | 201487/1060 | 9744 |

7590 09/10/2003
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EXAMINER

MARVICH, MARIA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1636

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,867

Applicant(s)

TAKAHASHI ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 September 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 and 11. 6) ☐ Other: ____.

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DETAILED ACTION

Claims 1-9 are pending in this application.

Specification

A substitute specification in proper idiomatic English and in compliance with 37 CFR 1.52(a) and (b) is required. The substitute specification filed must be accompanied by a statement that it contains no new matter. For example see page 1, line 32-34 "Specifically, their application to pedigree or lineage discrimination and individual identification of humans, animals, and plants is advanced." Also as an example see page 3, line 17-18, "The present invention provides a highly efficient isolation method that any known technique cannot attain."

Drawings

Formal drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed PTO-948.

Claim Objections

Claim 1 is objected to because of the following informalities: a period is missing for the end of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claim 9 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Burgtorf et al. Gene, Vol 137 (1993) pages 287-291, see entire document.

Burgtorf et al. teach a method for the isolation of "repetitive sequences" present in several telomeric regions of *Drosophila melanogaster* chromosomes (see e.g. p 287, column 2). The repetitive sequence GGGTCAT- satellite DNA is cloned following sonication and blunting by mung bean nuclease (see e.g. page 288, column 1, first paragraph). These sequences are used as markers of telomeres (see Figure 4b).

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Claims 1-3 and 7 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Bittner et al. US 5,663,319, see entire document.

Bittner et al. teach isolation of probes from "alpha" satellite sequences. Alphoid sequences are associated with centromeres and are a family of tandemly repeated DNA segments- that is based on monomer repeat lengths of about 171 base pairs (see e.g. column 5, line 10-17). The DNA is fragmented into fragments that are about 150 to 600 bp by sonication (see e.g. column 20 line 51 through column 21, line 57). The sequences are suited for use as markers of chromosome regions (see e.g. column 29, line 55 through column 30 line 16).

Claim Rejections - 35 USC § 103

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgtorf et al. in view of Promega et al.

Applicants claim a method for isolation of satellite sequences in which the DNA is fragmented by sonication and then blunt-ended by use of DNA polymerase with 3' to 5' exonuclease activity.

Burgtorf et al. teach a method for the isolation of "repetitive sequences" present in several telomeric regions of *Drosophila melanogaster* chromosomes (see e.g. p 287, column 2). The repetitive sequence GGGTCAT- satellite DNA is cloned following sonication and blunting by mung bean nuclease (see e.g. page 288, column 1, first paragraph). These sequences are used as markers of telomeres (see Figure 4b). Burgtorf et al. do not teach use or use DNA polymerase with 3' to 5' exonuclease activity.

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Promega teaches use of 3' to 5' exonuclease (Klenow) activity to generate blunt ends (see e.g. page 2, column 1, paragraph 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use Klenow fragments to generate blunt ends of the repetitive sequence GGGTCAT- satellite DNA following sonication taught by Burgtorf et al. because Promega teach that it is within the ordinary skill of the art to blunt end fragmented DNA and because Burgtorf et al. teach that it is within the ordinary skill of the art to blunt end fragmented DNA. One would have been motivated to do so in order to receive the expected benefit of generation of blunt ended fragments for efficient cloning. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4-5 is unclear for reciting that the genomic DNA is to be blunted. As the step of blunting is recited in the future tense, it is unclear when the DNA is to be blunted.

Claim 9 provides for the use of satellite sequences, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is

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intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-9 are unclear for reciting that randomly cleaved fragments of the genomic DNA are obtained. It is unclear if the step of obtaining the fragments is a positive action step that must be done by the practitioner or something that is already done in the prior art, it appears from reading the specification that the limitation of "obtaining" is meant to specify a positive action step of "producing" or "generating".

Conclusion

Claims 1-9 are rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maria B Marvich, PhD
Examiner
Art Unit 1636

September 4, 2003


GERRY LEFFERS
PRIMARY EXAMINER

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